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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,355	04/07/2004	Nasrola Edalatpour	101192.0001US1	8119
24392 7590 07/16/2007 FISH & ASSOCIATES, PC ROBERT D. FISH 2603 Main Street Suite 1050 Irvine, CA 92614-6232			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/820,355	EDALATPOUR, NASROLA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Claim Rejections 35 U.S.C. 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fawzi et al. (US 5,373,022), as evidenced by Remington's: the Science and practice of Pharmacy, Nineteenth Edition, Vol. 1, page 806.

Fawzi et al. teaches a pharmaceutical composition comprising a non-steroid anti-inflammatory drug and an antihistamine. in a preferred embodiment the non-steroid anti-inflammatory drug is ibuprofen or naproxen and antihistamine is ranitidine or cimetidine. The composition is particularly useful treatment of cough, cold, cold-like and/or flu symptoms. The composition may be in the forms for oral administration. See, particularly, col. 1, lines 58 to col. 2, line 26, col. 5, lines 11-46 and the claims. Remington's Science and Practice of Pharmacy, Nineteenth Edition, Vol. 1, page 806 teaches that the inclusion of a package insert including "indication and use" of pharmaceutical composition is mandated by 21 CFR 201.75. Further, it is well-settled that the content of printed matter with a composition does not carry patentable weight to the composition. See, *In re Ngai*, 70 USPQ 1862 (CA FC 2004).

### ***Claim rejections 35 U.S.C. 103***

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fawzi et al. (US 5,373,022), in view of Remington: the Science and practice of Pharmacy, Nineteenth Edition, Vol. 1, page 806, and in further view of Physicians' Desk Reference.

5. Fawzi et al. teaches a pharmaceutical composition comprising a non-steroid anti-inflammatory drug and an antihistamine. in a preferred embodiment the non-steroid anti-inflammatory drug is ibuprofen or naproxen and antihistamine is ranitidine or cimetidine. The composition is particularly useful treatment of cough, cold, cold-like and/or flu symptoms. The composition may be in the forms for oral administration. See, particularly, col. 1, lines 58 to col. 2, line 26, col. 5, lines 11-46 and the claims. Remington's Science and Practice of Pharmacy, Nineteenth Edition, Vol. 1, page 806 teaches that the inclusion of a package insert including "indication and use" of pharmaceutical composition is mandated by 21 CFR 201.75. Further, it is well-settled that the content of printed matter with a composition does not carry patentable weight to the composition. See, *In re Ngai*, 70 USPQ 1862 (CA FC 2004). Physician's Desk Reference reveal that ibuprofen and acetaminophen are well-known anti-inflammatory, antipyretic agents and the effective amounts is normally less than 1000 mg/day, and the ranitidine is normally less than 1500 mg/day. See, pages 1182, 1563, 1572.

6. Claims 15-20 are directed to arrangement of H2-histamine receptor antagonists, such as ranitidine and cimetidine, proximal to anti-pyretic analgesic or cold or flu medicine for sale or

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advertising sale of the H2-histamine receptor antagonists together with the anti-pyretic analgesic agents herein.

7. Such action would have been obvious to one of ordinary skill in the art at the time the claimed invention was made because the two drugs, are known to be used together for treatment of cough, cold, cold-like and/or flu symptoms.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang  
Primary Examiner  
Art Unit 1617

  
**SHENGJUN WANG**  
**PRIMARY EXAMINER**